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Attorneys for Plaintiff
OUTLAW LABORATORY, LP

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

OUTLAW LABORATORY, LP, a Texas limited partnership,

Plaintiff,

vs.

TREPCO IMPORTS & DISTRIBUTION, LTD. D/B/A TREPCO WEST D/B/A TREPCO SALES COMPANY D/B/A KENNEDY WHOLESALE, a Michigan Corporation, DAVID WEBBER D/B/A WHOLE SCIENCE HEALTH D/B/A PASSION PLUS, an individual, HILAL SOHAM TOMA D/B/A CITY SMOKES & VAPORS, an individual, HIGUCHI DEVELOPER, INC., a Nevada Corporation, ALPHA SMOKE SHOP

CASE NO. 18-cv-369

SECOND AMENDED COMPLAINT FOR:

(1) FALSE ADVERTISING IN VIOLATION OF THE LANHAM ACT § 43 (a)(1)(B)); AND

[DEMAND FOR A JURY TRIAL]

INC, a Nevada Corporation, MUKUND NAIK D/B/A JAY'S SMOKE SHOP & GIFT SHOP, an individual, RYAN STORE INC D/B/A A&A SMOKE SHOP, a Nevada Corporation, MIRACLE 21 CORPORATION D/B/A CIGARETTES FRAGRANCES, a Nevada Corporation, HIGH CLASS HOOKAH SHOP, L.L.C., a Nevada Limited Liability Company, JTR INCORPORATED D/B/A MR. BILL'S PIPE & TOBACCO COMPANY, a Nevada Corporation, and DOES 1 through 100, inclusive,

Defendants.

Plaintiff Outlaw Laboratory, LP, a Texas limited partnership ("OLP" or "Plaintiff"), by and through its undersigned attorneys, submits this Second Amended Complaint against defendant TREPCO IMPORTS & DISTRIBUTION, LTD. D/B/A TREPCO WEST D/B/A TREPCO SALES COMPANY D/B/A KENNEDY WHOLESALE, a Michigan Corporation ("Trepco" or "Defendant"), and in support thereof avers as follows:

INTRODUCTION

1. Trepco distributes misbranded "male enhancement" pills containing undisclosed pharmaceuticals to through a network of retail stores including the products Black Stallion 5000, Grande X 5800, Libigrow XXXtreme, Orgazen, Powerzen, Rhino 12 Titanium, Rhino 7 Platinum 5000, and Rhino 8 Platinum 8000 (collectively, the "Trepco Products"). All of the Enhancement Products have been the subject of laboratory testing and public announcements by the FDA, which found these products to contain hidden drug ingredients such as sildenafil (a prescription drug), desmethyl carbodenafil (an analogue of sildenafil), dapoxetine (an unapproved anti-depressant drug) and tadalafil (a prescription drug), among other dangerous undisclosed ingredients. Although this action has been pending for over a year, Trepco remains unrepentant for its conduct and continues to offer not only the Trepco Products but additional male enhancement products under the "Rhino" brand, including products Rhino Horny 66000, Rhino Horny 69000, and Rhino Mega 82000 (The "New Rhino Products"), even though these products are the subject of an FDA Press Release dated November 27, 2018. (Exhibit A).

2. Plaintiff is the manufacturer of competing products called "TriSteel" and "TriSteel 8hour," which are lawful male enhancement products made in the United States and distributed for sale in all 50 US States.

3. The illegal male enhancement supplement industry has flourished in the shadows of intermittent enforcement of nutritional supplement laws. In this regard, the

FDA has numerous public notices of which Trepco is well-aware regarding the use of sildenafil in over the counter "male enhancement" supplements but has only taken action on a handful of cases. Most recently in November of 2018, the FDA issued a press release "warning consumers not to purchase or use Rhino male enhancement products, due to a recent rise in reported health issues." ("FDA Press Release." Exhibit A) Since 2007, the FDA has identified hundreds of individual products, including "25 products marketed with variations of the name 'Rhino' that contained hidden drug ingredient(s)." Trepco has completely ignored the FDA notices, and ignored the detailed allegations in this lawsuit, despite the filing of the present lawsuit over a year ago.

4. Rather, Trepco continues its unlawful conduct unabated, claiming ignorance as to the gravity of the problem and making money all the while. In reality, Trepco is taking advantage of intermittent criminal enforcement of the supplements in the name of profits

5. Without robust enforcement of our laws, Plaintiff's only recourse is a civil action to protect the commercial interests recognized by the Lanham Act.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. § 1121 and 28 U.S.C. § 1331 (federal question jurisdiction).

7. This Court has personal jurisdiction over Defendant because it, directly or through their intermediaries (including distributors, retailers, and others), developed, licensed, manufactured, shipped, distributed, offered for sale, sold, and advertised their products, including but not limited to the Enhancement Products, in the United States, the State of Nevada and this district. Defendants have purposefully and voluntarily placed these products into the stream of commerce with the expectation that they will be purchased in this district.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions which gave rise to the claim occurred in this district.

PARTIES

9. Plaintiff Outlaw Laboratory, LP is a Texas limited partnership organized under the laws of the State of Texas.

10. Upon information and belief, Trepco Imports & Distribution, LTD. d/b/a Trepco West d/b/a Trepco Sales Company d/b/a Kennedy Wholesale (hereinafter "Trepco") is a Michigan Corporation with its principal place of business located at 1201 E Lincoln, Madison Hts, Michigan 48071. Trepco also maintains a warehouse in this district located at 3930 Civic Center Drive N. Las Vegas, NV 89030.

11. Plaintiff is ignorant of the true names and capacities of defendants sued herein as Does 1-100, inclusive, and therefore sued these defendants by such fictitious names. Plaintiff will amend this Complaint to allege their true names and capacities when ascertained. Plaintiff is informed and believes and thereon alleges that each of these fictitiously named defendants is responsible in some manner for the occurrences herein alleged, and that Plaintiff's injuries as herein alleged were proximately caused by the aforementioned defendants.

FACTUAL ALLEGATIONS

Sildenafil and Tadalafil Are Prescription Drugs

12. Sildenafil nitrate, better known as Viagra, and Tadalafil, better known as Cialis, are considered a prescription drugs under 21 U.S.C. Section 353(b)(1)(A) & (B). Because Sildenafil and Tadalafil are prescription drugs, the following limitations to its distribution and sale apply:

(A) ***because of its toxicity or other potentiality for harmful effect***, or the method of its use, or the collateral measures necessary to its use, ***is not safe for use except***

> ***under the supervision of a practitioner licensed by law to administer such drug***; or
>
> (B) ***is limited . . . to use under the professional supervision of a practitioner licensed by law to administer such drug***; ***shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist***, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

21 U.S.C. § 353(b)(1)(A) & (B) (emphasis added).

13. The FDA has approved sildenafil for treatment of erectile dysfunction. However, because of known side effects, drug interactions and contraindications, the FDA has deemed sildenafil to be a prescription drug that can only be administered under the supervision of a medical professional pursuant to 21 U.S.C. Section 353(b)(1)(A) & (B).

14. The serious side effects of these drugs, for example, priapism (i.e., prolonged penile erections leading to tissue death and potential permanent erectile dysfunction), severe hypotension (i.e., low blood pressure), myocardial infarction (i.e., heart attack), ventricular arrhythmias, stroke, increased intraocular pressure (i.e., increased eye fluid pressure), anterior optic neuropathy (i.e., permanent optic nerve damage), blurred vision, sudden hearing loss, and dizziness.

15. The serious negative drug interactions of these drugs include, for example, (i) interacting with alkyl nitrites and alpha-1 blockers to cause angina and life-threatening hypotension, (ii) interacting with protease inhibitors to increase the incidence and

severity of side effects of sildenafil alone, and (iii) interacting with erythromycin and cimetidine to cause prolonged plasma half-life levels.

16. In addition to these risks, contraindications of these drugs include underlying cardiovascular risk factors (such as recent heart surgery, stroke or heart attack) since consumption of sildenafil by individuals with these conditions can greatly increase the risk of heart attack.

17. Because of these dangerous side effects, drug interactions and contraindications, the advice and authorization of appropriate licensed medical professionals is absolutely crucial for the safe consumption of sildenafil. Without such safeguards, the consequences can be dire; the sale of mislabeled sildenafil in similar circumstances has led to multiple deaths reported in the media.

The Male Enhancement Product Shadow Economy

18. The FDA has been aware of the problem of mislabeled sildenafil and tadalafil for several years. FDA laboratory analyses have confirmed that the hundreds of similar products contain undisclosed drugs.[1]

19. The FDA recently issued a press release indicating the epidemic in November of 2018, and the Department of Justice has recently taken action indicting a distributor of these products. (See, Exhibits A-B)

20. The products sold all share common traits, detailed in more depth below. Typically, the products contain overt false statements, including that they are "ALL NATURAL," a "NATURAL FORMULA," with "NO HARMFUL synthetic chemicals" and "NO PRESCRIPTION necessary" and other affirmative misrepresentations regarding the Enhancement Products' legality and safety.

[1] The current list of products tested by the FDA can be found at: https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm234539.htm

21. As the FDA recognized in its November 2018 press release, the scheme to sell mislabel prescription drugs pose extreme health risks to consumers in at least two ways. First, by stating that no prescription is necessary to consume the Enhancement Products, perpetrators of this scheme mislead consumers into believing that the advice and authorization of a licensed medical professional is not required to mitigate or avoid the potentially life-threatening side effects, drug interactions and contraindications of sildenafil hidden in the Enhancement Products. Second, by failing to inform consumers that the Enhancement Products contain sildenafil, consumers who know that their medical history and drug prescriptions make sildenafil consumption dangerous may nevertheless consume the subject products because they are unaware that they contain sildenafil.

22. Accordingly, false and misleading advertising of these products is extremely dangerous to individual consumers and harmful to the dietary supplement industry as a whole. The scheme creates an illegitimate marketplace of consumers seeking to enhance their sexual performance but who are not informed, or who are misinformed, of the serious dangers of what they consume. The ubiquity of over-the-counter misbranded male enhancement products, their relatively low cost to manufacture in comparison to natural products, and their dramatic pharmacologic effects makes it so that manufacturers and suppliers of legitimate sexual performance enhancement products, such as TriSteel or TriSteel 8hour who do not engage in false and misleading advertising, struggle to obtain market share.

Trepco's Role In Disseminating the False Representations

23. At the time of the filing of the original complaint, Trepco offered for sale various misbranded drugs, including Rhino 8 Platinum 8000, Rhino 12 Titanium 6000 and Libigrow XXXTreme, and persists to this day. (See current Product List of Trepco West attached as Exhibit C) Pursuant to a January 24, 2018 email Plaintiff was able to obtain, a true and correct copy of which is attached as Exhibit D, Trepco supplied Former

Defendant Higuchi with Rhino 8 Platinum 8000, Rhino 12 Titanium 6000 and Libigrow XXXTreme. Former Defendant Higuchi in turn has tacitly conceded to offering Rhino 8 Platinum 8000, Rhino 12 Titanium 6000 and Libigrow XXXTreme for sale up until December 19, 2017. Higuchi forwarded a communication from a "David Ruh" of Trepco stating that many stores had "come in to shop" from Trepco, and that "[a]ll the products that we carry are ok otherwise we would not be selling[.]" These statements are unequivocally false.

24. The current Product List of Trepco West (Relevant portions attached as Exhibit C) and available for download from www.trepco.com/trepco-west contains numerous prohibited male enhancement pills for sale under the label "vitamins", including Black Stallion 5000, Grande X 5800, Libigrow XXXtreme, Orgazen, Powerzen, Rhino 12 Titanium, Rhino Seven Platinum 5000, and Rhino 8 Platinum 8000 (the "Trepco Products").

25. All of the above products are misbranded as detailed below. (See FDA notices attached as Exhibit E For example, Grande X 5800 has been the subject of a product recall due to containing Sildenafil; Libigrow XXXtreme has been found by the FDA to contain Sildenafil; Orgazen has been found by the FDA to contain Sildenafil; Powerzen has been found by the FDA to contain Sildenafil; Rhino 12 Titanium has been found by the FDA to contain Sildenafil; Rhino 7 Platinum 5000 Titanium has been found by the FDA to contain Sildenafil; Rhino 8 Platinum 8000 has been found by the FDA to contain Sildenafil.

The New Rhino Products

26. When not selling products directly identified by the FDA as being misbranded, Trepco, like many distributors of misbranded male enhancement pills, play a cat-and-mouse game with the FDA where the FDA tests certain products and publicly announces their illegal contents, whereupon distributors like Trepco simply varies the name of the Rhino pill so that the pill does not come under the ambit of the FDA

announcement. One example of this scheme is Trepco's sale of Black Stallion 5000. Black Stallion 3500, a product that is virtually identical in its labeling besides the modifier "3500," has been the subject of previous FDA announcements (Exhibit E) Trepco now sells "Black Stallion 5000" so that it can have plausible deniability should its business practices come under scrutiny. Similarly, as detailed below, while Rhino Seven Platinum 5000 has been found to contain sildenafil, Trepco attempts to avoid culpability by selling a product called Rhino Seven Platinum 3000, the only difference, again, is the numerical modifier.

27. Trepco repeats this pattern with all of the Rhino Products it sells through its DBA, Kennedy Wholesale. Attached hereto as Exhibits F and G are a true and correct copies of the salient portions of a "Kennedy Wholesale – A Division of TrepcoWest Order Book," which changed its catalog from 2018 to 2019 to contain modified names of the illicit products. Thus, after the filing of the present complaint and while Trepco's motion to dismiss was pending in 2018, Trepco simply changed the name of the Rhino Products it offers for sale through it's Kennedy Wholesale DBA from Rhino 8 Platinum 8000 and Rhino 12 Titanium 6000 to Rhino Horny 66000, Rhino Horny 69000, and Rhino Mega 82000 (The "New Rhino Products")(Compare, Exhibits F (1/18/2018 "Kennedy Wholesale Order Book" and Exhibit G, 1/16/2019 ""Kennedy Wholesale Order Book")

28. The FDA has been made aware of the cat-and-mouse game, and made clear in its November 2018 announcement warning consumers not to purchase or use Rhino male enhancement products, "due to a recent rise in reported health issues." The press release noted that "[s]ince 2007, the FDA has identified more than 25 products marketed with variations of the name "Rhino" that contained hidden drug ingredient(s)" and that "FDA has received reports of people experiencing chest pain, severe headaches and prolonged erections after taking a Rhino product that led to surgical intervention and

hospitalization due to extreme drops in blood pressure" as a result of taking Rhino branded products.

29. The New Rhino products disseminated by Trepco and its affiliates fall within the scope of the FDA's warning, and all bear similar false statements, including (1) that they are a "dietary supplement;" (2) that they are "FDA registered" and (3) that they contain "herbs, powders, and extracts" and bear no mention of the illegal contents on its ingredient label (The labels of the New Rhino Products are attached as Exhibit H)

30. The statements on these products, disseminated by Trepco and its subsidiaries, are false. First, since the new products contain drugs, they cannot be "dietary supplements" as that term is defined by federal law.

31. Second, their display of the term "FDA Registered" has been explicitly condemned by the FDA as false and misleading (Exhibit I). Most recently, in a March 11, 2019 warning letter, the FDA explicitly said that the use of the phrase is "false or misleading" since the FDA does not register dietary supplements, rather "it is drug establishments that are subject to registration with FDA." Thus, according to the FDA, to state that a product is "'FDA Registered' is inaccurate; drugs are subject to listing with FDA, not registration. Moreover, registration …does it mean that a product may be legally marketed. (21 CFR 207.77(a))." Despite the regulatory framework, the FDA recognized in its November 2018 Press Release that "the general public is not likely to be familiar with the details of FDA regulation" and "the assertion of 'FDA Registered' status in conjunction with the [sale of products] misleadingly suggests that …products are themselves approved or endorsed by FDA in some way when this is not true." Thus, use of the FDA Registered moniker on the New Rhino Products makes the products "misbranded under section 502(a) of the FD&C Act, 21 U.S.C. 352(a), because their labeling is false or misleading…"

32. Finally, the New Rhino products false statement that they contain "herbs, powders, and extracts" and bear no mention of the illegal contents on its ingredient label"

is again false and misleading, as testing of the Rhino products and the FDA's November 2018 Press Release indicate.

Plaintiff's Dietary Supplements: TriSteel and TriSteel 8hour

33. Plaintiff OLP is a manufacturer of DSHEA-compliant dietary supplements. Plaintiff manufactures and offers for sale TriSteel and TriSteel 8hour, male sexual performance enhancement supplements that promote increased sexual desire and stamina. The ingredients in TriSteel are Epimedium Extract (leaves), Yohimbe Extract (8mg Yohimbine Alkaloids), Xanthoparmelia Scarbrosa Extract (Lichen), Gamma Amino Butyric Acid (GABA), L-Arginine, Gelatin, Cellulose, Magnesium Stearate and Silica. Plaintiff sells TriSteel and TriSteel 8hour in all 50 states through its website, as well as through many other online and storefront retail locations. Plaintiff is in direct competition with those who manufacture, sell, distribute and market sexual performance enhancement products.

34. Although Plaintiff supports fair and free competition, false and misleading claims such as those made by Defendants are beyond the pale, in that they market the Trepco Products and the New Rhino Products as safe and natural and that they bear indicia of government approval. In fact, the opposite is true. The Trepco Products and the New Rhino Products are not safe, as they have led to many reported health problems according to the FDA. The products are not natural, because they contain pharmaceuticals that can only be administered by a doctor according to the FDA. Finally, the products do not have governmental approval --- in fact that the opposite is true. Trepco's continued sale of these products after being put on notice by this lawsuit, and the FDA's continued enforcement and press releases is patently unfair and will mislead consumers to Trepco's competitive benefit, to Plaintiff's competitive injury, and to the serious injury of consumers.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(False Advertising in Violation of Section 43(a)(1)(B) of the Lanham Act)

35. Plaintiff incorporates the allegations contained in the foregoing paragraphs as though fully set forth herein in their entirety.

36. Trepco has knowingly and purposely made false and misleading descriptions of fact concerning the nature, characteristics and qualities of the Trepco Products and the New Rhino Products by, without limitation, commercially marketing and claiming that the Enhancement Products that they sell are safe and natural "dietary supplements" that will enhance a consumer's sexual performance without requiring a doctor's prescription, all while purposefully omitting that (a) the Enhancement Products contain sildenafil and therefore cannot be "dietary supplements," (b) sildenafil is not naturally occurring, (c) sildenafil is a prescription drug requiring the prior authorization and supervision of a licensed medical professional, and (d) consumption of sildenafil without consultation and advice from a licensed medical professional poses extreme health risks, including without limitation, hypotension, heart attack and death. Trepco fails to disclose any of the FDA's warnings, recalls and press releases regarding the legality of the products or their safety.

37. The use of such false, misleading and disingenuous marketing has the tendency to deceive a substantial segment of the public and consumers, including those in this district, into believing that they are purchasing a product with different characteristics.

38. This deception is material because: (i) it is likely to influence a consumer's purchasing decision, especially if the consumer (a) is looking for an all-natural sexual enhancement dietary supplement, (b) is purchasing the Enhancement Products out of an attempt to avoid Sildenafil because the consumer knows that Sildenafil poses special health risks given such consumer's medical history or current drug prescriptions, and/or (c) wants to avoid taking any prescription drugs, generally, but especially without the

supervision of a licensed medical professional; and (ii) such decision could lead to dangerous and unanticipated health consequences for such consumers.

39. Trepco has introduced their false and misleading statements into interstate commerce via marketing and advertising on product packages and labels, and on display cases placed in retail locations in the state of Nevada.

40. Plaintiff has been injured as a result of Trepco's false and misleading statements. Specifically, Trepco's dissemination of false and misleading advertising concerning the Enhancement Products has negatively impacted Plaintiff's sales of TriSteel and TriSteel 8hour because both products are intended for sexual performance enhancement and target the same consumers. Thus, Plaintiff has suffered both an ascertainable economic loss of money and reputational injury by the diversion of business from Plaintiff to Defendants and the loss of goodwill in Plaintiff's products. The ubiquity of the Enhancement Products, their relatively low cost to manufacture in comparison to natural products (like TriSteel and TriSteel 8hour), and their dramatic pharmacologic effects makes it so that legitimate sexual performance enhancement products, such as TriSteel or TriSteel 8hour, struggle to obtain market share. Moreover, Defendants conduct has created reputational damage in that Defendants' misconduct damages the marketplace as a whole and has the tendency to disparage Plaintiff's products and goodwill.

41. Defendants' actions, as described above, constitute false and misleading descriptions and misrepresentations of fact in commerce that, in commercial advertising and promotion, misrepresent the nature, characteristics, and qualities of its products in violation of Section 43(a)(1)(B) of the Lanham Act.

PRAYER

Wherefore, Plaintiff OLP prays for judgment against Defendants as follows:

1. For preliminary and permanent injunctive relief enjoining Defendant from producing, licensing, marketing, and selling any of the Trepco Products or the New Rhino Products;
2. For an award of compensatory damages to be proven at trial in accordance with 15 U.S.C. § 1117;
3. For an award of any and all of Defendant's profits arising from the foregoing acts in accordance with 15 U.S.C. § 1117 and other applicable laws;
4. For restitution of Defendant's ill-gotten gains;
5. For treble damages in accordance with 15 U.S.C. § 1117;
6. For costs and attorneys' fees; and
7. Any other relief the Court may deem appropriate.

DATED: March 25, 2019

BLUT LAW GROUP, PC

By: /s/ Elliot S. Blut
Elliot S. Blut, Esq.
Attorneys for Plaintiff
OUTLAW LABORATORY, LP

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury.

DATED: March 25, 2019

BLUT LAW GROUP, PC

By: /s/ Elliot S. Blut
Elliot S. Blut, Esq.
Attorneys for Plaintiff
OUTLAW LABORATORY, LP